

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administra Seattle District Pacific Region 22201 23rd Drive SE Bothell, WA 98021-4421

Telephone: 425-486-8788 FAX: 425-83-4996

April 1, 2002

VIA CERTIFIED MAIL RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-38

Jeffrey T. Buck, Owner All American Feed & Tractor 502 West Alder Street Sandpoint, Idaho 83864

WARNING LETTER

Dear Mr. Buck:

An investigation at your feed mill and rendering operation located at 502 West Alder Street, Sandpoint, Idaho, conducted by a Food and Drug Administration investigator on March 5, 2002, found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 - Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured and distributed by your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigation found that you failed to maintain sufficient records and written procedures to prevent cross contamination [21 CFR 589.2000] in that:

- 1. Sufficient records are not maintained to track prohibited animal proteins throughout receipt, processing, and distribution. No records are maintained to document the order in which feeds were produced to demonstrate that a chicken feed flush was made after a dog feed containing prohibited material [21 CFR 589.2000(c)(ii)].
- 2. Written procedures are not maintained to prevent commingling or cross-contamination between feed containing prohibited animal proteins from feed intended for ruminants [21 CFR 589.2000(e)(iv)].
 - There are no written procedures for cleaning out or flushing equipment after mixing feeds containing prohibited material.
 - There are no written procedures for separating products that contain or may contain prohibited material from ingredients used in ruminant feeds, from the time of receipt until the time of shipment.

Jeffrey T. Buck, Owner All American Feed & Tractor, Sandpoint, Idaho Re: Warning Letter SEA 02-38 Page 2

The above is not intended to be an all-inclusive list of deficiencies at your facility. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations, and prevent their recurrence. If corrective action cannot be completed in fifteen (15) working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Althar, Compliance Officer at (425) 483-4940.

Sincerely.

Charles M. Breen District Director